K112357

NOV 10 2011

SECTION 1. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for Vessel Vapor™

SUBMITTER'S NAME:	LEXION Medical LLC
ADDRESS:	545 Atwater Circle St. Paul, MN 55103
CONTACT PERSON:	Bernard (Bud) Horwath
TELEPHONE NUMBER:	651-361-8041
FAX NUMBER:	651-351-8001
DATE OF SUBMISSION:	12 August 2011

1. **Identification of device**
   Proprietary Name: Vessel Vapor™
   Common Name: Laparoscopic Insufflator Gas Conditioner
   Classification Status: Class II per regulations 884.1730
   Product Code: HIF

2. **Equivalent devices**
   LEXION Medical believes that Vessel Vapor™ is substantially equivalent to the following devices:
   Vessel Guardian®, K102136
   Insu*flow*®, K090456

   Vessel Vapor™ is the same gas conditioner insufflator accessory device and has the same intended use as the predicate devices cleared under 510(k) K102136 and K090456.

3. **Description of the Device**
   The Vessel Vapor™ device is a single use device that attaches to the outlet port of an insufflator or other regulated CO_2 source and is designed to warm and humidify the CO_2 gas stream prior to insufflation into the surgical cavity. The Vessel Vapor™ device consists of a disposable tubing set with a filter and heater/humidifier cassette and a control module that houses the control and safety circuits for the system.

   Regulated CO_2 gas flows into the Vessel Vapor™ device, through the in-line filter, continues along the tube to enter the Vessel Vapor™ device cassette that contains the heating element and humidification media, through a tube that connects via a Luer lock connector to a gas entrance port or an insufflation needle/trocar and finally flows into the patient's surgical cavity.

4. **Intended use**

Vessel Vapor™ is a gas conditioner accessory device intended to heat, humidify and filter an insufflating CO_2 gas stream being used in minimally invasive cardiovascular, thoracoscopic, and vessel harvesting surgical procedures.

The indications for use for the Vessel Vapor™ are patterned after the predicate devices; however, they have been expanded to include minimally invasive cardiovascular surgical procedures. The addition of this specific indication does not affect the safety and effectiveness of the device when used as labeled.

5. **Technological characteristics, comparison to predicate device.**

Technically, the Vessel Vapor™ is identical to the Vessel Guardian® and Insu*flow*® devices cleared for market in 510(k) K102136 and K090456, respectively.

6. **Conclusion**

Based on a comparison to the predicate devices, it is the conclusion of LEXION Medical that Vessel Vapor™ is substantially equivalent to devices already on the market being used for this application (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Bernard Horwath
Regulatory Consultant
LEXION Medical LLC
545 Atwater Circle
ST PAUL MN 55103

NOV 10 2011

Re: K112357
Trade/Device Name: Vessel Vapor™
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF, OSV
Dated: August 12, 2011
Received: August 16, 2011

Dear Mr. Horwath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number K112357

Device Name: Vessel Vapor™

Indications for Use:

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112357